

Application Serial No. 09/720,762

Attorney Docket No. 114174.00014

Amendment and Response to Office Action, Submitted June 30, 2006

**REMARKS/ARGUMENTS**

Claims 1, 3 and 6-9, 11 and 13-40 are now pending, a total of 35 claims. Claims 1, 9, 22 and 32 are independent.

**I. New Matter and Written Description Rejections**

The Office Action mailed December 30, 2005 raised § 132 "new matter" and § 112, first paragraph issues relating to the phrase "wherein the restriction that is not laminated" in claims 1 and 9. Independent claims 1 and 9, as amended, meet the requirements of 35 U.S.C. §§ 112 and 132. No new matter has been introduced. See, e.g., original claim 3.

**II. Independent Claim 1**

Claims 1, 3, 6-17 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull (U.S. 6,080,136), and Ito (U.S. 5,063, 025). Independent claim 1 recites as follows:

1. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin.

Neither reference teaches or suggests laminating some surfaces of a syringe gasket and leaving others unlaminated. Trull does not teach or suggest any gasket coating. Ito does not teach or suggest selectively applying a coating to gasket surfaces, let alone the

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selectively laminating in the manner recited in claim 1. Thus, nothing in Trull or Ito – individually or in combination – teach or suggest laminating “only the peripheral side surface that contacts the inner surface of the syringe barrel,” as recited in claim 1.

Further, the Office Action asserts that it would have been obvious to modify the Trull gasket by using the polyethylene or polypropylene coating of Ito. The Office Action cites no evidence in support of this assertion. To establish prima facie obviousness, motivation to combine references must be supported by “substantial evidence” of what was known before the invention was made (MPEP § 2143.01, 2144.-2144.09), not mere conclusory statements about what might be “basic knowledge” or “common sense” to one of ordinary skill in the art years later during examination. *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001). Therefore, if any rejection is maintained, Applicant respectfully requests a reference or an affidavit to support any alleged “motivation to combine” Trull with Ito to apply a coating to “only the peripheral side surface that contacts the inner surface of the syringe barrel.” See 37 C.F.R. § 1.104(d)(2).

Claim 1 is patentable over any combination of Trull and Ito, and no proper combination has been shown. Claim 1 may be allowed.

### III. Independent Claim 9

Independent claim 9 recites as follows:

9. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a first tapered slant, and a second tapered slant is formed between the peripheral

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side surface of the gasket that contacts the inner surface of the syringe barrel and the restriction.

Neither reference teaches or suggests laminating a "peripheral side surface" of a syringe gasket with a resin, such that the assembly is suitable for injecting fluids into a human body. As stated above, Trull does not teach laminating a syringe gasket whatsoever. Ito does not teach coating a gasket for liquids injected into the human body.

The Ito plunger is intended for "an analytical microsyringe [for] gas chromatography and liquid chromatography." (Column 1, lines 7-9.) The Ito coating protects the plunger from the corrosive effects of the acidic gaseous and liquid samples that are used for chromatographic analysis. Ito does not disclose medical applications for its plunger. Further, Ito teaches a linear plunger, not a tapered gasket. Thus, the Ito plunger is non-analogous art and not reasonably pertinent to the problem being solved by the syringe gasket of Claim 9. *In re Clay*, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992) And the Office Action has offered no evidence to the contrary.

For at least the reasons discussed above, claim 9 is also patentable over the combination of Trull and Ito.

#### IV. Independent claim 23

New independent claim 23 recites as follows:

23. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin.

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As discussed, the art of record does not teach or suggest coating a tapered gasket with polyethylene fluoride resin. Thus, independent claim 23 is patentable over the cited references.

#### **V. Independent Claim 33**

New independent claim 33 recites as follows:

33. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with silicon.

Independent claim 33 is patentable over the art of record. None of the cited references teach or suggest a silicon coating for a tapered gasket and, in particular, silicon for "the peripheral side surface that contacts the inner surface of the syringe barrel," as recited in Claim 33.

#### **VI. Dependent Claims**

Dependent claims 3, 6-8, 10-22, 24-32 and 34-41 are patentable with the independent claims discussed above. These dependent claims recite additional features that further distinguish the cited references.

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In view of the foregoing, Applicant respectfully submits that the claims are in condition for allowance and therefore requests reconsideration of the application. The Examiner may telephone Applicant's undersigned counsel at the number below concerning prosecution of this application.

Also enclosed is a Petition for Extension of Time for three (3) months, and a Request for Continued Examination.

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